

Appl. No. : 09/574,819  
Filed : May 19, 2000

## REMARKS

Claims 27-32 are pending in this application. The claims have been amended to conform to the consensus embodiment described in Example 4 and Figure 4. No new matter has been added. Reexamination and reconsideration of the application, as amended, are respectfully requested.

### A. Compliance with 35 USC 102

Submitted herewith is a declaration to establish completion of the invention of this application in the United States at a date prior to 25 March 1994, which is the effective filing date of U.S. Patent 5,658,882 to Celeste et al. accorded by the examiner, 102(e) prior art in terms of date. The declaration incorporates by reference the declarations mailed on 09/29/2003, 07/08/2004, and 12/02/2005 to swear behind 14 April 1994, the date that appeared on Storm et al. Nature 368:639-643 (1994), which was previously cited by the examiner, 102(a) prior art in terms of date. The date of 25 March 1994 is only about 3 weeks before the date of 14 April 1994.

The persons making this declaration are the named co-inventors.

The inventors affirm that the declaration mailed 09/29/2003 shows the completion of a partial bovine DNA sequence encoding a partial amino acid sequence comprising the amino acid sequence of SEQ ID NO: 24 and that the acts performed by Applicants described therein did occur before the date of 25 March 1994.

The inventors affirm that the declaration mailed 07/08/2004 shows completion of the bovine species of the claimed invention and that the acts performed by Applicants described therein did occur before the date of 25 March 1994.

The inventors affirm that the declaration mailed 12/02/2005 shows completion of a partial *Xenopus* DNA sequence encoding a partial amino acid sequence comprising the amino acid sequence of SEQ ID NO: 24 and that the acts performed by Applicants described therein did occur before the date of 25 March 1994.

From these declarations, it can be seen that the invention described in the application was made at a date prior to 25 March 1994.

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**B. Compliance with 35 USC 103**

The Patent Office rejected the claims under 35 USC 103(a) as being unpatentable over a primary reference and Neidhardt PCT/EP93/00350, published 19 August 1993. Under the statute, a patent may not be obtained if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made. Neidhardt is admitted not to describe a sequence encoding a protein comprising SEQ ID NO: 24, only expression vectors, host cells, and processes for the production of proteins. The declaration establishes completion of the invention of this application at a date prior to 25 March 1994, let alone 14 April 1994. At the time the invention was made, Neidhardt's description of only expression vectors, host cells, and processes for the production of proteins could not have rendered the subject matter as a whole obvious because a sequence encoding a protein comprising SEQ ID NO: 24 was unknown. The secondary reference does not fill in the gap left by the antedating of the primary reference, thus the rejection cannot prevail.

**C. Compliance with Rules Against Double Patenting**

This is a provisional obviousness-type double patenting rejection of Claim 27 over claims 10 and 11 of copending Application No. 10/379,830. The other claims have not in fact been patented. The solution is to pass this application to issuance and make the rejection in the other application nonprovisional.

**D. Separate Patentable Invention under 35 USC 102(g)**

The issue is whether the claims define a separate patentable invention under 35 USC 102(g) or conflict with USP 5,770,444 to Lee et al. The rule according to Eli Lilly & Co. v. Bd. of Regents of the Univ. of Wash., 67 USPQ2d 1161 (Fed. Cir. 2003) is that the two-way test is required for determining whether two parties claim the "same patentable invention". A "separate patentable invention" means that the species invention of one party is new and nonobvious in view of the genus invention of the other party. Id. at p. 1164. Here, application of the two-way test leads to the determination that USP 5,770,444 to Lee et al. and the claims of the present application do not define the same patentable invention. The claims of the present application are directed to a genus. USP 5,770,444 to Lee et al. describes a species. Comparing NIH (the

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present Applicant) and USP 5,770,444 to Lee et al., USP 5,770,444 to Lee et al. describes a species falling within the genus of NIH. The species of USP 5,770,444 to Lee et al. is not rendered obvious by NIH's genus considering the size of the genus. Given that NIH's 31 amino acid sequence (SEQ ID NO: 24) can be extended in the amino and carboxy direction by insertion of any of 20 different amino acids at any one site to a total length of 134 amino acids (SEQ ID NO: 6 of USP 5,770,444 to Lee et al.), the number of possibilities embraced by the NIH genus is almost infinite. The number of possibilities equals on the order of:

$$20^{103} \approx 10^{134} .$$

Absent anything in the prior art suggesting which of the almost infinite possibilities embraced by NIH's genus corresponds to USP 5,770,444 to Lee et al., the prior art would not have suggested the claimed species. Although a genus may be so small that, when considered in light of the totality of the circumstances, it would anticipate the claimed species, not so here. Remembering that it embraces a number of possibilities that is almost infinite, the NIH genus cannot inherently anticipate the claimed species of USP 5,770,444 to Lee et al. because one skilled in the art would not envisage each member of the genus. Besides the size of the genus, a consideration of any teachings of a "typical" or "preferred" or "optimum" species within the disclosed genus reveals that any such teaching is nonexistent. Although a clone encoding a mature CDMP-2 (aka GDF-6) would have been advantageous, its sequence was unknown. Besides the size of the genus and lack of teachings to support the selection of the species, unexpected advantages reside in the claimed species of USP 5,770,444 to Lee et al. being an actual clone, of mouse, encoding a mature CDMP-2 (aka GDF-6). Given the size of the genus, the lack of teachings to support the selection of the species, and the unexpected advantages, the conclusion is that the species of USP 5,770,444 to Lee et al. defines a separate patentable invention from the genus of the present application under 35 USC 102(g). No interference-in-fact exists.

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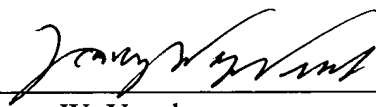
### CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 5/15/06

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AMEND

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